The Federal Register Publication System:

WHAT IT IS
AND
HOW TO USE IT

Office of the Federal Register
National Archives and Records Administration
2008

Introduction

Welcome to the Federal Register Workshop

Presenter:

Jim Hemphill

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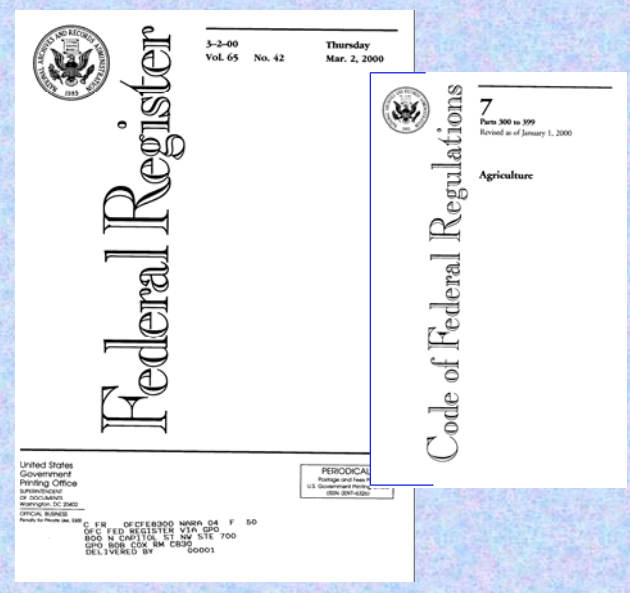
- GPO: www.gpoaccess/fr

What topics will this workshop cover ?

- Historical background and legal basis
- The regulatory process and the role of the public
- Organization the *Federal Register* and CFR
- Relationships among Public Laws, the FR and CFR
- Research tools and Finding Aids

Historical Background & Legal Basis



Why was the Federal Register System Established ?

- New Deal legislation
- Access
- Centralized filing and publication system
- Due process rights

Federal Regulatory Process

- Legal structure:
  - ✧**The Federal Register Act**
  - ✧**The Administrative Procedure Act (APA)**
  - ✧**Other individual laws**
- Designed to allow Federal agencies to issue and enforce legally effective regulations

Introduction

The Federal Register Act

Enacted: July 26, 1935 Cite: 44 U.S.C. Chap. 15

- Established a **central location**
- **The daily *Federal Register***
- **The *Code of Federal Regulations***

Introduction

The Effect of Publishing in the *Federal Register*

- Official notice
- Legal authority of the agency
- Documents evidentiary status
- Shows how and when the CFR will be amended

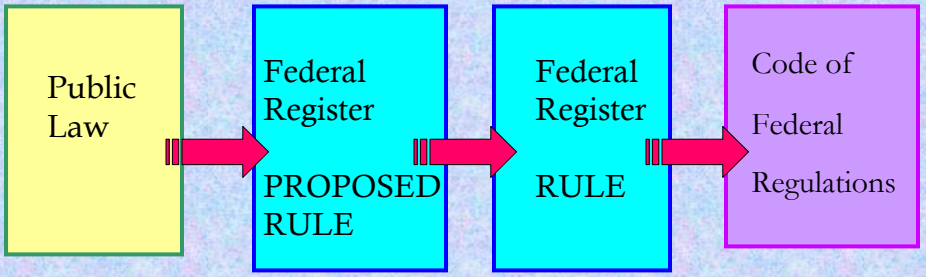
The Administrative Procedure Act

Enacted: June 11, 1946 Cite: 5 U.S.C. 551 et seq.

Added procedural requirements to ensure:

- ✧**due process** (fairness)
- ✧**public participation** (notice and comment rulemaking)

The Regulatory Process



Introduction

Overview of Rulemaking Process

1. Grant of rulemaking authority
2. Proposed Rule stage
3. Final Rule stage
4. Congressional review
5. Effective date

Introduction

Comparison of Laws and Rules

Congress Passes Laws	Executive Agencies Issue Rules
Publish in Slip Law/Statutes at Large Codified in U.S. Code	Publish in Federal Register Codified in CFR
Power comes from Constitution	Power delegated by Congress
Courts review for constitutionality	Courts review for constitutionality & limits of delegated authority arbitrary and capricious actions Administrative Procedure Act reqs.
Representative Democracy: Congress acts collectively to represent the will of the people	Participatory Democracy: Agencies must seek and consider public comment on benefits of rules v. burdens and costs
Set broad social and economic goals and legal requirements	Prescribe specific legal requirements to meet goals

The Daily *FEDERAL REGISTER*

Federal Register

The *Federal Register*

- **An official daily legal publication**
- **Informs citizens of:**
  - ✧**rights and obligations**
  - ✧**opportunities for funding and Federal benefits**
  - ✧**actions of Federal agencies for accountability to public**
- **Citation:** 64 FR 34567 (June 5, 1999)

Federal Register

Federal Register Documents

1. Presidential Documents
2. Rules and Regulations
3. Proposed Rules
4. Notices

Additional sections:

- Corrections
- Separate Parts
- Reader Aids

Proposed Rules

What Types of documents are in the Proposed Rules section ?

- Proposed Rules
  - ✧ AKA: “Notice of Proposed Rulemaking” (NPRM)
- Preliminary Rulemaking Documents
- Miscellaneous proposals and updates

Proposed Rules

Proposed Rule

- Announces possible changes to the CFR
- Sets out proposed regulatory text or describes proposal
- Solicits public comment on proposal
- Initiates the "notice and comment rulemaking" process under the APA (5 U.S.C. 553)

Proposed Rules

Standard Preamble Headings & Captions

Headings ➡ Agency name, CFR title and part(s), docket info, subject matter

Captions ⬇

- AGENCY:
- ACTION:
- SUMMARY:
- DATES:
- ADDRESSES:
- FOR FURTHER INFORMATION CONTACT:
- SUPPLEMENTARY INFORMATION:

Proposed Rules

Advance Notices and Preliminary Rulemaking Documents

Advance Notice of Proposed Rulemaking

Petition for Rulemaking

Negotiated Rulemaking ("RegNeg") document

Proposed Rules

Miscellaneous Proposed Rule Documents

- **Extension of time to submit comments on proposed rule**
- **Further notice of proposed rulemaking to make changes in response to comments or events**
- **Withdrawal of proposed rule**
- **Annual review of regulations -- opportunity to comment**

What is the Rules and Regulations Section of the *Federal Register* ?

- **Documents with:**
  - ✧**Final legal effect**
  - ✧**General applicability to the public**
- **Most, rules amend and are codified in the CFR**

What Types of Documents are in the Rules & Regulations Section ?

- **Final Rules**
- **Interim Final Rules**
- **Direct Final Rules**
- **Documents that relate to previous rules & regulations**

Final Rule

- Generally issued to amend the CFR
- Finalizes a proposed rule
- Takes final action without a prior proposed rule
- Effective Dates:
  - ✧ At least 30 days from date of publication
  - ✧ At least 60 days from date of publication for major rules
  - ✧ On date of publication
    - » emergency
    - » good cause

Standard Preamble Headings & Captions

Headings ➡ Agency name, CFR title and part(s), docket info, subject matter

Captions ⬇

- AGENCY:
- ACTION:
- SUMMARY:
- DATES:
- ADDRESSES:
- FOR FURTHER INFORMATION CONTACT:
- SUPPLEMENTARY INFORMATION:

Rules and Regulations:
Final Rule

Final Rule Amendments and Regulatory Text

- Follow the "Supplementary Information" section of the Preamble
- The "List of Subjects"
- Numbered amendatory instructions specifically state how the CFR will be amended

Rules and Regulations:
Interim Final Rule

Interim Final Rule

Issued:

- ✧ To react to an emergency situation
- ✧ To relieve unnecessary restrictions on the public
- ✧ To take public comments on interim action

Effective:

- ✧ On date of publication; or
- ✧ Less than 30 days from date of publication

Comment Period:

- ✧ Yes

Rules and Regulations:
Direct Final Rule

Direct Final Rule

Issued:

- Non-controversial actions

Effective:

- 30, 60 to 90 days from date of publication, if it is not withdrawn due to adverse comments

Is there a comment period?

- Yes

Withdrawn:

- Monitor the *Federal Register* for a withdrawal document

Rules and Regulations:
Other

Documents that Relate to Previous Rules & Regulations

Examples:

- Interpretive Rule; Policy Statement on Enforcement; Clarification
- Temporary Rule; Deviation; Waiver
- Establishment, Delay, Suspension of Effective Date
- Reconsideration of recently issued Final Rule
- Withdrawal or Confirmation of Direct Final Rule

CONTINUE

Notices

Documents in the Notices section of the FR

Describing official actions and functions that:

- ✧ May affect the public or provide important information BUT Do not amend the CFR.

Examples:

- ✧ Sunshine Act and Federal Advisory Committee Act meeting notices
- ✧ Grant announcements and funding availability
- ✧ Environmental impact statements

Notices

What is the format for Notices ?

Headings ➡ Agency name, docket info, subject matter, no CFR cite

Captions ⬇

- **AGENCY:**
- **ACTION:**
- **SUMMARY:**
- **DATES:**
- **ADDRESSES:**
- **FOR FURTHER INFORMATION CONTACT:**
- **SUPPLEMENTARY INFORMATION:**

Presidential Documents

What Presidential Documents are published in the Federal Register ?

- Executive Orders
- Proclamations
- Administrative Orders & Miscellaneous Documents

Presidential Documents

Executive Orders

- Directed at Executive agencies to manage operations
- President has constitutional authority to issue E.O.s as
- Numbered consecutively as received by OFR
- Reprinted annually in 3 CFR, not codified

Presidential Documents

Original of Executive Order

Typewritten manuscript

EXECUTIVE ORDER

- - - - - - -

PRESIDENT'S INFORMATION TECHNOLOGY ADVISORY COMMITTEE, FURTHER AMENDMENTS TO EXECUTIVE ORDER 13035, AS AMENDED

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the High-Performance Computing Act of 1991 (Public Law 102-194), as amended by the Next Generation Internet Research Act of 1998 (Public Law 105-305) ("Research Act"), and in order to extend the life of the President's Information Technology Advisory Committee so that it may carry out the additional responsibilities given to it by the Research Act, it is hereby ordered that Executive Order 13035, as amended ("Executive Order 13035"), is hereby further amended as follows:

Section 1. The preamble of Executive Order 13035 is amended by addition after "("Act")," the phrase "as amended by the Next Generation Internet Research Act of 1998 (Public Law 105-305) ("Research Act"),".

Sec. 2. Section 2 of Executive Order 13035 is amended by adding a subsection "(a)" after the heading and before the first sentence and by adding a new subsection "(b)" after the last sentence to read as follows: "(b) The Committee shall carry out its responsibilities under the Research Act in the manner described in the Research Act."

Sec. 3. Section 4(b) of Executive Order 13035 is amended by deleting "two years from the date of this order" and inserting "February 11, 2001," in lieu thereof.

William J. Clinton

Original signature

THE WHITE HOUSE,
February 10, 1999.

Presidential Documents

Executive Order Published in FR

This E.O. amends a prior E.O.

Changes are not integrated in the CFR

By law, E.O.s are compiled, not codified

7489

Federal Register
Vol. 64, No. 30
Tuesday, February 16, 1999

Presidential Documents

Title 3—
The President

Executive Order 13113 of February 10, 1999

President's Information Technology Advisory Committee, Further Amendments to Executive Order 13035, as Amended

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the High-Performance Computing Act of 1991 (Public Law 102-194), as amended by the Next Generation Internet Research Act of 1998 (Public Law 105-305) ("Research Act"), and in order to extend the life of the President's Information Technology Advisory Committee so that it may carry out the additional responsibilities given to it by the Research Act, it is hereby ordered that Executive Order 13035, as amended ("Executive Order 13035"), is hereby further amended as follows:

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William J. Clinton

THE WHITE HOUSE,
February 10, 1999.

[FR Doc. 99-3832
Filed 2-12-99; 8:45 am]
Billing code 3195-01-P

Sequential number assigned to this E.O.

Presidential Documents

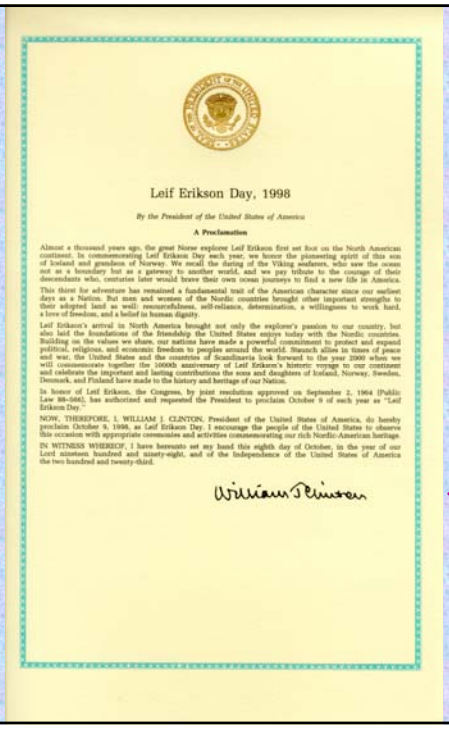
Proclamations

- **TYPES**
  - ✧Ceremonial
  - ✧Substantive
- **Numbered consecutively as received by OFR**
- **No legal distinction between E.O.s &**
- **Reprinted annually in 3 CFR, not codified**

Presidential Documents

Original of Ceremonial Proclamation

Printed on parchment style paper



Leif Erikson Day, 1998

By the President of the United States of America

A Proclamation

Almost a thousand years ago, the great Norse explorer Leif Erikson first set foot on the North American continent. In commemorating Leif Erikson Day each year, we honor the pioneering spirit of this son of Iceland and grandson of Norway. We recall the daring of the Viking seafarers, who saw the ocean not as a boundary but as a gateway to another world, and we pay tribute to the courage of their descendants who, centuries later would brave their own ocean journeys to find a new life in America.

This thirst for adventure has remained a fundamental trait of the American character since our earliest days as a Nation. But men and women of the Nordic countries brought other important strengths to their adopted land as well: resourcefulness, self-reliance, determination, a willingness to work hard, a love of freedom, and a belief in human dignity.

Leif Erikson's arrival in North America brought not only the explorer's passion to our country, but also laid the foundations of the friendship the United States enjoys today with the Nordic countries. Building on the values we share, our nations have made a powerful commitment to protect and expand political, religious, and economic freedom to peoples around the world. Staunch allies in times of peace and war, the United States and the countries of Scandinavia look forward to the year 2000 when we will commemorate together the 1000th anniversary of Leif Erikson's historic voyage to our continent and celebrate the important and lasting contributions the sons and daughters of Iceland, Norway, Sweden, Denmark, and Finland have made to the history and heritage of our Nation.

In honor of Leif Erikson, the Congress, by joint resolution approved on September 2, 1964 (Public Law 88-566), has authorized and requested the President to proclaim October 9 of each year as "Leif Erikson Day."

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, do hereby proclaim October 9, 1998, as Leif Erikson Day. I encourage the people of the United States to observe this occasion with appropriate ceremonies and activities commemorating our rich Nordic-American heritage.

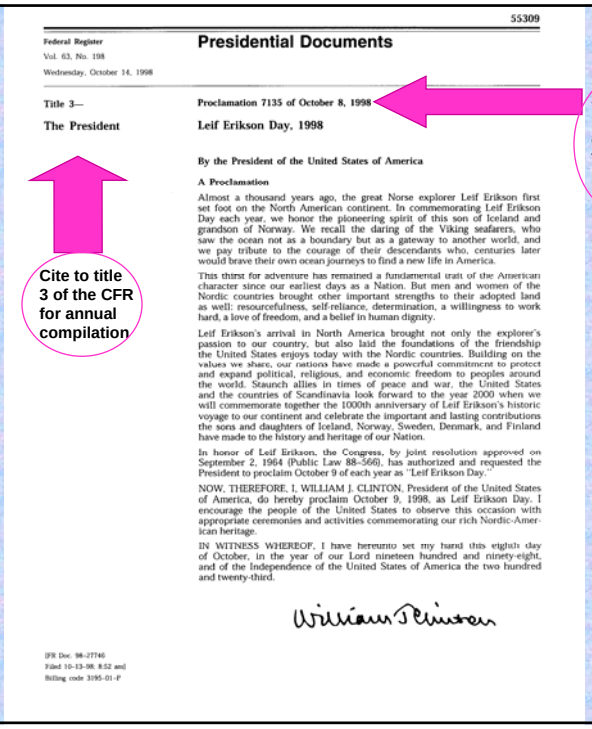
IN WITNESS WHEREOF, I have hereunto set my hand this eighth day of October, in the year of our Lord nineteen hundred and ninety-eight, and of the Independence of the United States of America the two hundred and twenty-third.

William J. Clinton

Original signature

Presidential Documents

Proclamation Published in FR



55309

Federal Register
Vol. 63, No. 198
Wednesday, October 14, 1998

Presidential Documents

Title 3—
The President

Proclamation 7135 of October 8, 1998

Leif Erikson Day, 1998

By the President of the United States of America

A Proclamation

Almost a thousand years ago, the great Norse explorer Leif Erikson first set foot on the North American continent. In commemorating Leif Erikson Day each year, we honor the pioneering spirit of this son of Iceland and grandson of Norway. We recall the daring of the Viking seafarers, who saw the ocean not as a boundary but as a gateway to another world, and we pay tribute to the courage of their descendants who, centuries later would brave their own ocean journeys to find a new life in America.

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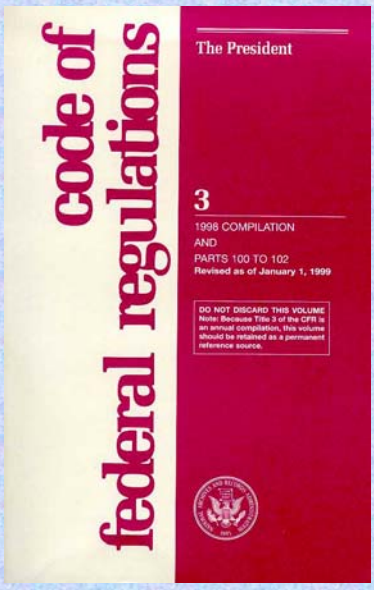
William J. Clinton

[FR Doc. 98–27746
Filed 10–13–98; 8:52 am]
Billing code 3195–01–P

Sequential number assigned to this Proclamation

Cite to title 3 of the CFR for annual compilation



Presidential Documents

Administrative Orders and Miscellaneous Documents

- Determinations
- Memoranda
- Reorganization Plans
- Notices of Continuation of National Emergencies

Comprehensive record of Presidential statements and directives:

- Weekly Compilation of Presidential Documents
- Public Papers of the Presidents series

Corrections

Federal Register Correction section

OFR or GPO **typographical and clerical errors**

We set out specific information necessary to correct error based on text of signed original.

Agencies **correct their errors by publishing a signed original in the appropriate category.**

Separate Parts

Separate Parts

- Appear at the end of the daily *Federal Register* issue
- Agencies request
  - ✧ For high profile documents.
  - ✧ To group related Final Rules, Proposed Rules and Notices together
- OFR places late arriving documents in separate parts for production purposes

FR Research Tools

Daily

FEDERAL

REGISTER

Finding Aids

&

Research Tools


Federal Register

3–2–00 Vol. 65 No. 42 Thursday Mar. 2, 2000

United States Government Printing Office
SUPERINTENDENT OF DOCUMENTS
Washington, DC 20402

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(ISSN 0097-6326)

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Daily *Federal Register* Research Tools and Finding Aids

- Table of Contents
- CFR Parts Affected in this Issue
- Reader Aids

Researching Information

- In today's *Federal Register*
- In previous *Federal Registers*

How can I find information in today's *Federal Register* ?

- ***Federal Register*** **Table of Contents:**
  - ✧ **Online edition has hypertext links to each document in the issue**
- ***CFR Parts Affected In This Issue***
  - ✧ **Accessible from search page of online edition**

FR Research Tools:
Today's FR

Federal Register Table of Contents

- **Arranged by agency name in alphabetical order**
- **Cross-references**
- **Each agency document is arranged by category**
- **Presidential Documents are arranged as follows:**
  - ✧ **Executive Orders**
  - ✧ **Proclamations**
  - ✧ **Determinations/Memoranda**

FR Research Tools:
TOC

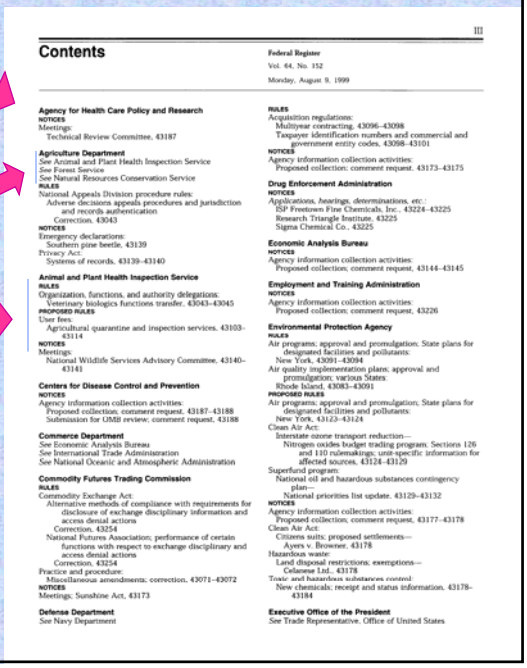
How is the Federal Register Table of Contents arranged ?

Documents listed by agency in alphabetical order

Cross-references from cabinet departments to sub-agencies

Documents arranged by category:

- Rules
- Proposed Rules
- Notices



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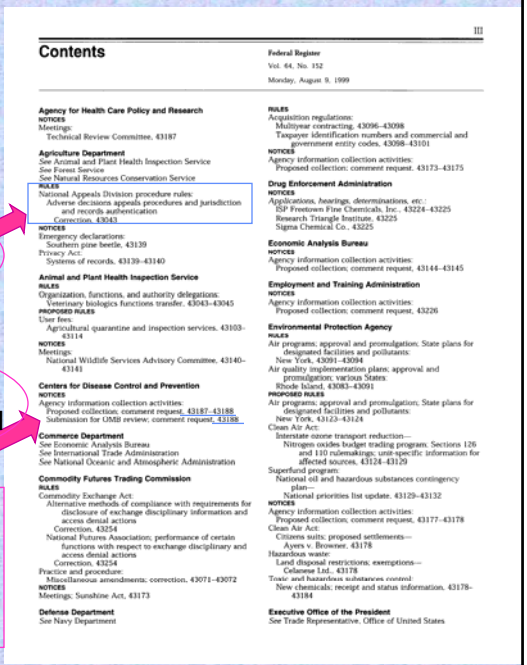
What information can I find in Contents entries ?

Each document has a brief description of subject matter

Page Numbers show the span of pages from beginning to end

A list of any “Separate Parts” in the issue appears at the end of the Table of Contents



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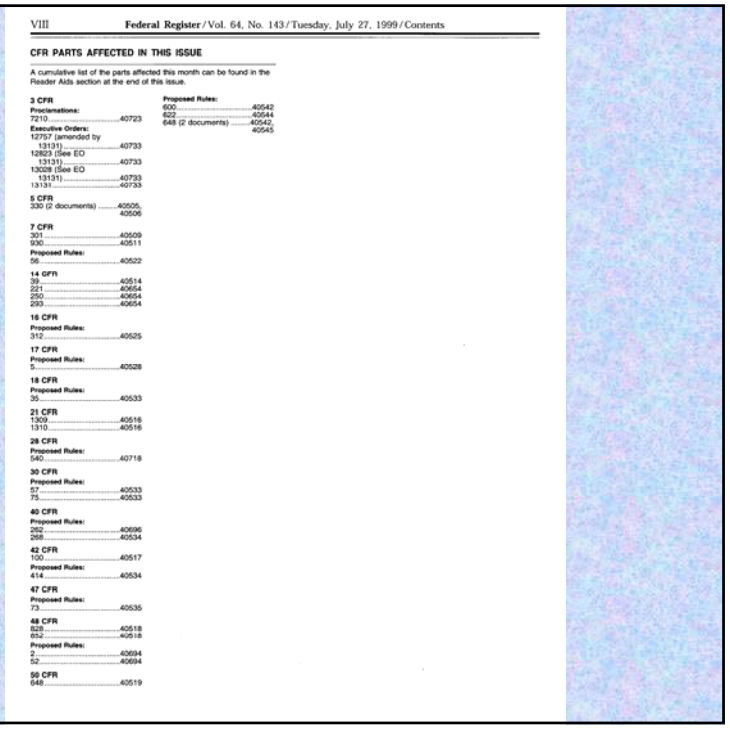
FR Research Tools:
Parts Affected

CFR Parts Affected in this Issue

- Located after the Table of Contents
- Lists CFR titles and parts affected in an issue
- Indicates whether the documents affecting CFR parts are rules or proposed rules
- Lists the number designations of all Presidential documents in the issue
- Cites the page numbers where relevant documents begin

FR Research Tools:
Parts Affected

CFR Parts Affected in this Issue



VIII Federal Register / Vol. 64, No. 143 / Tuesday, July 27, 1999 / Contents

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

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7210 40723
Executive Orders:
12757 (amended by 13131) 40733
12823 (See EO 13131) 40733
13028 (See EO 13131) 40733
13131 40733

5 CFR
330 (2 documents) 40505, 40506

7 CFR
301 40509
930 40511
Proposed Rules:
56 40522

14 CFR
39 40514
221 40654
250 40654
293 40654

16 CFR
Proposed Rules:
312 40525

17 CFR
Proposed Rules:
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Proposed Rules:
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21 CFR
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28 CFR
Proposed Rules:
540 40718

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Proposed Rules:
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262 40696
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52 40694

50 CFR
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600 40542
622 40544
648 (2 documents) 40542, 40545

Reader Aids

- **In the back of each daily FR issue**
- **Information on recent FR activity and new laws**
- **Include:**
  - ✧ ***CFR Parts Affected During*** **(the current month)**
  - ✧ **FR *Pages and Dates* (the current month)**
  - ✧ **OFR customer service information including:**

CFR Parts Affected During (the current month)

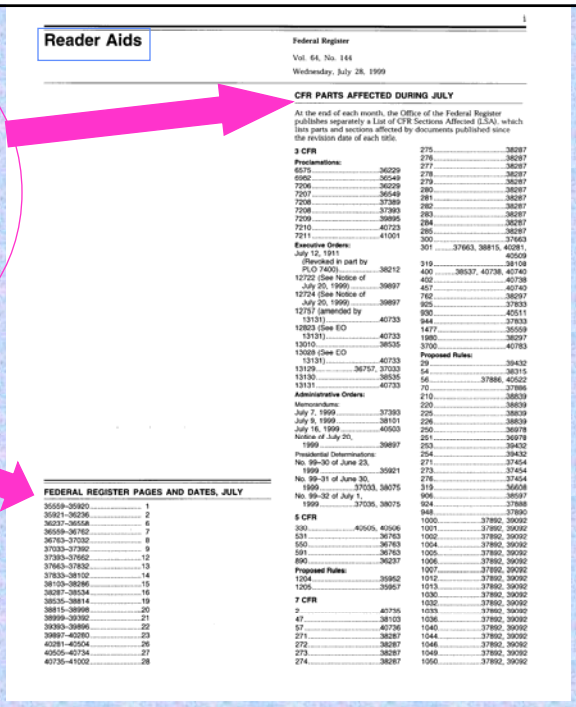
- **Cumulative table**
- **Lists documents in numerical order by CFR title and part**
- **You can quickly determine:**
  - ✧ **The CFR titles and parts affected by documents published during the current month**
  - ✧ **Whether the documents affecting the CFR parts are rules or proposed rules**
  - ✧ **The number designation of Presidential documents published during the current month**
  - ✧ **The page numbers where the relevant documents begin**

FR Pages and Dates (the current month)

- Cumulative table of page spans and dates
- Page spans are on the left side of the table with corresponding dates of publication on the right side
- Use the date table with entries from the *CFR Parts Affected During (the current month)* to find the date a document was published in FR

CFR Parts Affected During (the current month)

FR Pages and Dates



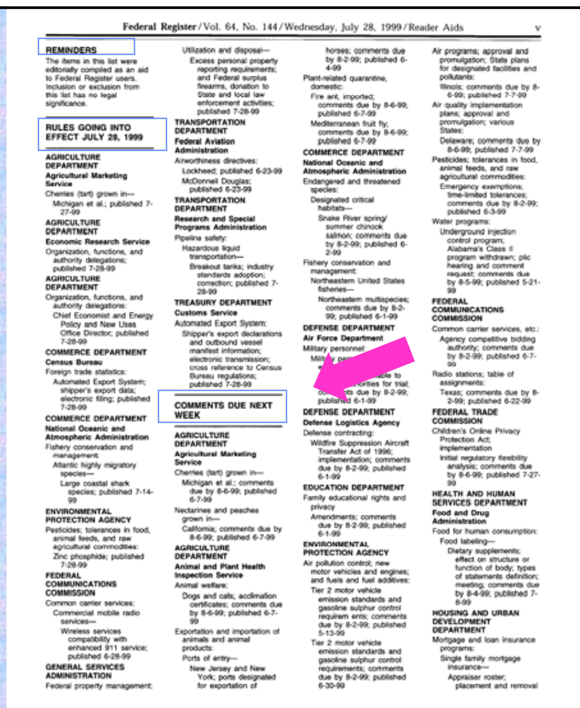
Reader's Aids

Reminders

- ***Rules Going Into Effect*** **(the current day) reminds you of rule documents that become effective on the current day**

- ***Comments Due Next Week*** **reminds you of previously published proposed rule documents that have comment deadlines the following week**

Reminders



Federal Register / Vol. 64, No. 144 / Wednesday, July 28, 1999 / Reader Aids v

REMINDERS

The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

RULES GOING INTO EFFECT JULY 28, 1999

AGRICULTURE DEPARTMENT
Agricultural Marketing Service
Cherries (tart) grown in—
Michigan et al.; published 7-27-99

AGRICULTURE DEPARTMENT
Economic Research Service
Organization, functions, and authority delegations; published 7-28-99

AGRICULTURE DEPARTMENT
Organization, functions, and authority delegations:
Chief Economist and Energy Policy and New Uses Office Director; published 7-28-99

COMMERCE DEPARTMENT
Census Bureau
Foreign trade statistics:
Automated Export System; shipper's export data; electronic filing; published 7-28-99

COMMERCE DEPARTMENT
National Oceanic and Atmospheric Administration
Fishery conservation and management:
Atlantic highly migratory species—
Large coastal shark species; published 7-14-99

ENVIRONMENTAL PROTECTION AGENCY
Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:
Zinc phosphide; published 7-28-99

FEDERAL COMMUNICATIONS COMMISSION
Common carrier services:
Commercial mobile radio services—
Wireless services compatibility with enhanced 911 service; published 6-28-99

GENERAL SERVICES ADMINISTRATION
Federal property management:
Utilization and disposal—
Excess personal property reporting requirements; and Federal surplus firearms, donation to State and local law enforcement activities; published 7-28-99

TRANSPORTATION DEPARTMENT
Federal Aviation Administration
Airworthiness directives:
Lockheed; published 6-23-99
McDonnell Douglas; published 6-23-99

TRANSPORTATION DEPARTMENT
Research and Special Programs Administration
Pipeline safety:
Hazardous liquid transportation—
Breakout tanks; industry standards adoption; correction; published 7-28-99

TREASURY DEPARTMENT
Customs Service
Automated Export System:
Shipper's export declarations and outbound vessel manifest information; electronic transmission; cross reference to Census Bureau regulations; published 7-28-99

COMMENTS DUE NEXT WEEK

AGRICULTURE DEPARTMENT
Agricultural Marketing Service
Cherries (tart) grown in—
Michigan et al.; comments due by 8-6-99; published 6-7-99
Nectarines and peaches grown in—
California; comments due by 8-6-99; published 6-7-99

AGRICULTURE DEPARTMENT
Animal and Plant Health Inspection Service
Animal welfare:
Dogs and cats; acclimation certificates; comments due by 8-6-99; published 6-7-99
Exportation and importation of animals and animal products:
Ports of entry—
New Jersey and New York; ports designated for exportation of horses; comments due by 8-2-99; published 6-4-99
Plant-related quarantine, domestic:
Fire ant, imported; comments due by 8-6-99; published 6-7-99
Mediterranean fruit fly; comments due by 8-6-99; published 6-7-99

COMMERCE DEPARTMENT
National Oceanic and Atmospheric Administration
Endangered and threatened species:
Designated critical habitats—
Snake River spring/summer chinook salmon; comments due by 8-2-99; published 6-2-99
Fishery conservation and management:
Northeastern United States fisheries—
Northeastern multispecies; comments due by 8-2-99; published 6-1-99

DEFENSE DEPARTMENT
Air Force Department
Military personnel:
Mili[illegible] able to [illegible]orities for trial; co[illegible]nts due by 8-2-99; published 6-1-99

DEFENSE DEPARTMENT
Defense Logistics Agency
Defense contracting:
Wildfire Suppression Aircraft Transfer Act of 1996; implementation; comments due by 8-2-99; published 6-1-99

EDUCATION DEPARTMENT
Family educational rights and privacy
Amendments; comments due by 8-2-99; published 6-1-99

ENVIRONMENTAL PROTECTION AGENCY
Air pollution control; new motor vehicles and engines; and fuels and fuel additives:
Tier 2 motor vehicle emission standards and gasoline sulphur control requirem ents; comments due by 8-2-99; published 5-13-99
Tier 2 motor vehicle emission standards and gasoline sulphur control requirements; comments due by 8-2-99; published 6-30-99
Air programs; approval and promulgation; State plans for designated facilities and pollutants:
Illinois; comments due by 8-6-99; published 7-7-99
Air quality implementation plans; approval and promulgation; various States:
Delaware; comments due by 8-6-99; published 7-7-99
Pesticides; tolerances in food, animal feeds, and raw agricultural commodities:
Emergency exemptions; time-limited tolerances; comments due by 8-2-99; published 6-3-99
Water programs:
Underground injection control program; Alabama's Class II program withdrawn; plic hearing and comment request; comments due by 8-5-99; published 5-21-99

FEDERAL COMMUNICATIONS COMMISSION
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Agency competitive bidding authority; comments due by 8-2-99; published 6-7-99
Radio stations; table of assignments:
Texas; comments due by 8-2-99; published 6-22-99

FEDERAL TRADE COMMISSION
Children's Online Privacy Protection Act; implementation
Initial regulatory flexibility analysis; comments due by 8-6-99; published 7-27-99

HEALTH AND HUMAN SERVICES DEPARTMENT
Food and Drug Administration
Food for human consumption:
Food labeling—
Dietary supplements; effect on structure or function of body; types of statements definition; meeting; comments due by 8-4-99; published 7-8-99

HOUSING AND URBAN DEVELOPMENT DEPARTMENT
Mortgage and loan insurance programs:
Single family mortgage insurance—
Appraiser roster; placement and removal

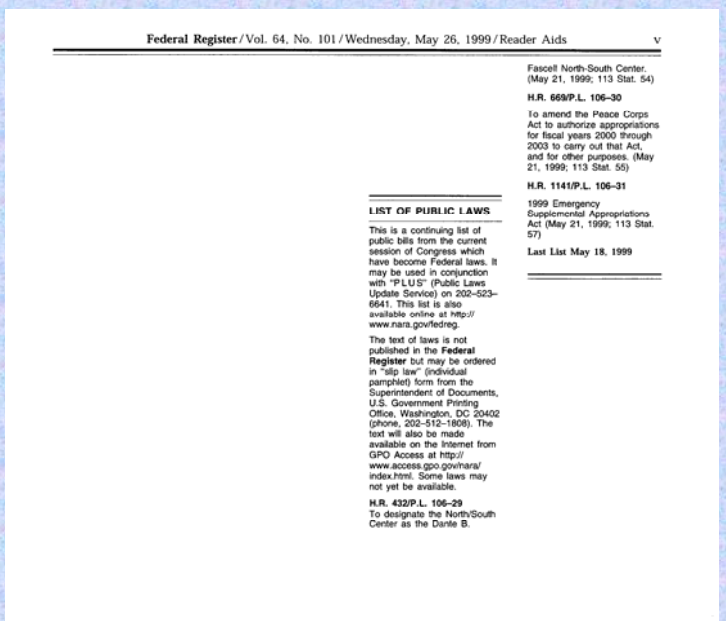
FR Research Tools:
Reader Aids

List of Public Laws & PENS

- **Identifies new Public Laws by:**
  - ✧ **Their House or Senate Bill or Resolution Numbers**
  - ✧ **The Public Law number**
  - ✧ **The popular name**
- **PENS subscription information (Public Laws Electronic Notification Service).**
  - ✧ **Free e-mail service for info on newly enacted public laws**

FR Research Tools:
Reader Aids

List of Public Laws



Federal Register / Vol. 64, No. 101 / Wednesday, May 26, 1999 / Reader Aids v

Fascell North-South Center. (May 21, 1999; 113 Stat. 54)

H.R. 669/P.L. 106–30

To amend the Peace Corps Act to authorize appropriations for fiscal years 2000 through 2003 to carry out that Act, and for other purposes. (May 21, 1999; 113 Stat. 55)

H.R. 1141/P.L. 106–31

1999 Emergency Supplemental Appropriations Act (May 21, 1999; 113 Stat. 57)

Last List May 18, 1999

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "PLUS" (Public Laws Update Service) on 202–523–6641. This list is also available online at http://www.nara.gov/fedreg.

The text of laws is not published in the **Federal Register** but may be ordered in "slip law" (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO Access at http://www.access.gpo.gov/nara/index.html. Some laws may not yet be available.

H.R. 432/P.L. 106–29
To designate the North/South Center as the Dante B.

FR Research Tools:
Previous FR

How can I find documents in past *Federal Register* issues?

Daily Federal Register (print edition)

- Index to CFR Parts Affected During Current Month

Federal Register Index (print edition)

- cumulative subject index of documents updated monthly

LSA (List of CFR Sections Affected).

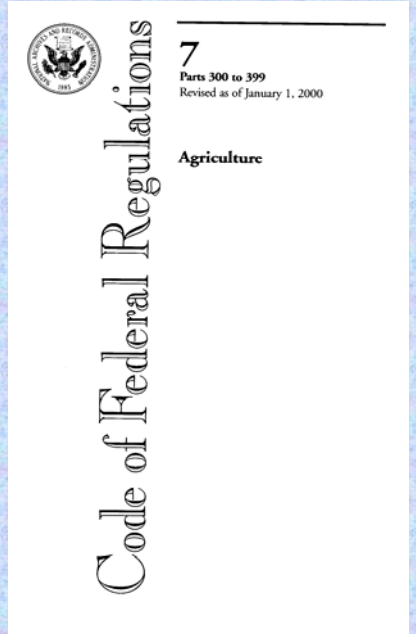
- printed monthly and online: www.access.gpo.gov/nara/lsa/aboutlsa.html
- numerical listing of changes keyed to CFR parts/sections

Search the *Federal Register* Online.

- Search by category, subject matter, date, and page number to retrieve documents from 1995 through present day
- Hypertext Table of Contents for each day since Jan. 1998

CONTINUE

The CFR -- ORGANIZATION & CONTENTS



CFR

What is the Code of Federal Regulations ?

- The CFR contains Federal rules that have:
  - ✧ General applicability to the public
  - ✧ Current and future effect as of the date specified
- Always published first in the FR as amendments to the CFR
- The CFR is published in a set of about 200 volumes
  - ✧ Printed soft cover books
  - ✧ Microfiche
  - ✧ Online at: www.access.gpo.gov/nara

CFR

How is the CFR organized ?

- Federal regulations are organized into:
  - ✧ 50 titles
  - ✧ Broad subject matter categories
    - » Environment, Defense, Public Health, Transportation
- Each title is completely revised and reissued once each year on a staggered schedule.
  - ✧ Titles 1 -- 16 updated as of January 1
  - ✧ Titles 17 -- 27 updated as of April 1
  - ✧ Titles 28 -- 41 updated as of July 1
  - ✧ Titles 42 -- 50 updated as of October 1

CFR

What is the CFR numbering system ?

- The CFR has a uniform numbering system
  - ✧ Titles 3, 41, and 48 have significant variations
- The section is the basic unit of the CFR
- Cite the CFR by title and section: 12 CFR 303.1
- Text is divided into descending levels of units

CFR

CFR Structure

Title	12	Broad subject area of regulations
Chapter	III	Rules of individual agency
Part	303	Rules on a single program or function
Section	303.1	One provision of program/function rules
Paragraph	303.1(a)	Detailed, specific requirements

CFR

Paragraph Levels

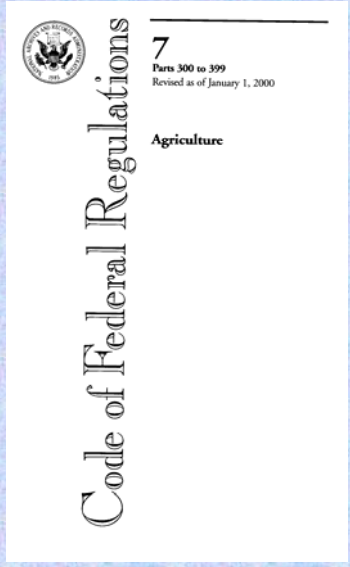
Sections may contain up to 6 levels of paragraphs.

- ✧ **We strongly recommend no more than 3 levels.**

Paragraph	Designations	Cite paragraph as
Level 1	(a), (b), (c), etc.	§ 303.1(a)
Level 2	(1), (2), (3), etc.	§ 303.1(a)(1)
Level 3	(i), (ii), (iii), etc.	§ 303.1(a)(1)(i)
Level 4	(A), (B), (C), etc.	§ 303.1(a)(1)(i)(A)
Level 5	*(1), (2), (3)*, etc.	§ 303.1(a)(1)(i)(A)*(1)*
Level 6	*(i), (ii), (iii)*, etc.	§ 303.1(a)(1)(i)(A)*(1)(i)*

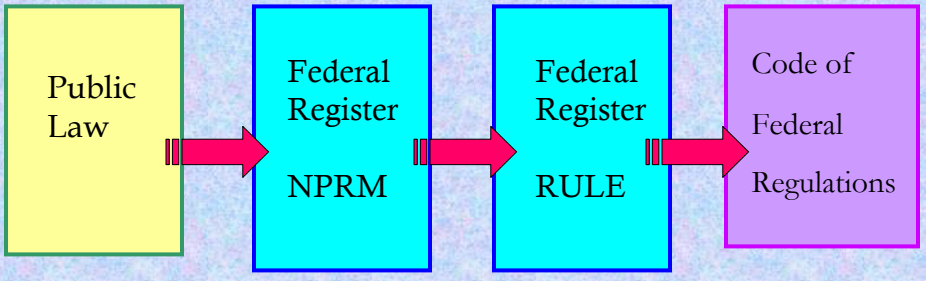
How are rules codified in the CFR ?

The Rulemaking Process from Start to Finish



Rulemaking Process

The Regulatory Process



What Triggers Rulemaking ?

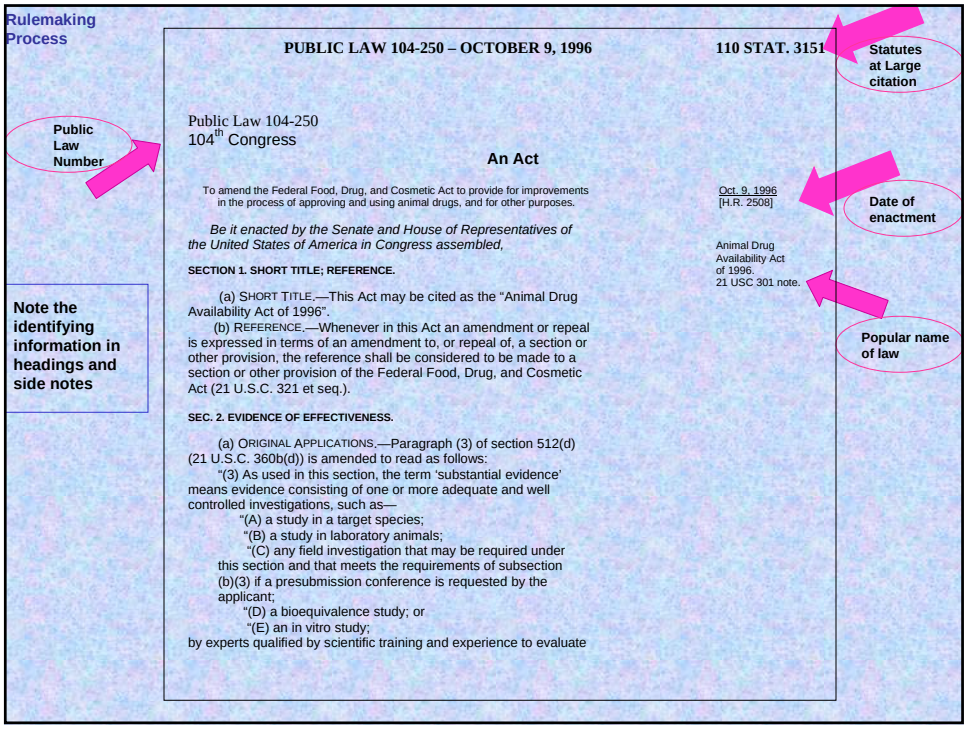
- Legislation, Congressional hearings/reports
- Executive orders and OMB Circulars
- Court Orders
- Agencies act on own initiative to carry out mission
- Petitions for Rulemaking and informal requests from affected parties
- Federal Advisory Committee Recommendations
- Emergency situations, technological developments
- Political Factors

Authorization in Public Law

Rulemaking usually begins with Congressional action.

For Example:

- ✧ **The Animal Drug Availability Act of 1996 (ADAA) (Public Law 104- 250), enacted October 9, 1996, amended the Food, Drug and Cosmetic Act.**
  - » **Signaled Congressional intent for Food and Drug Administration (FDA) to administer the regulations on behalf of the Secretary of Health and Human Services (HHS).**

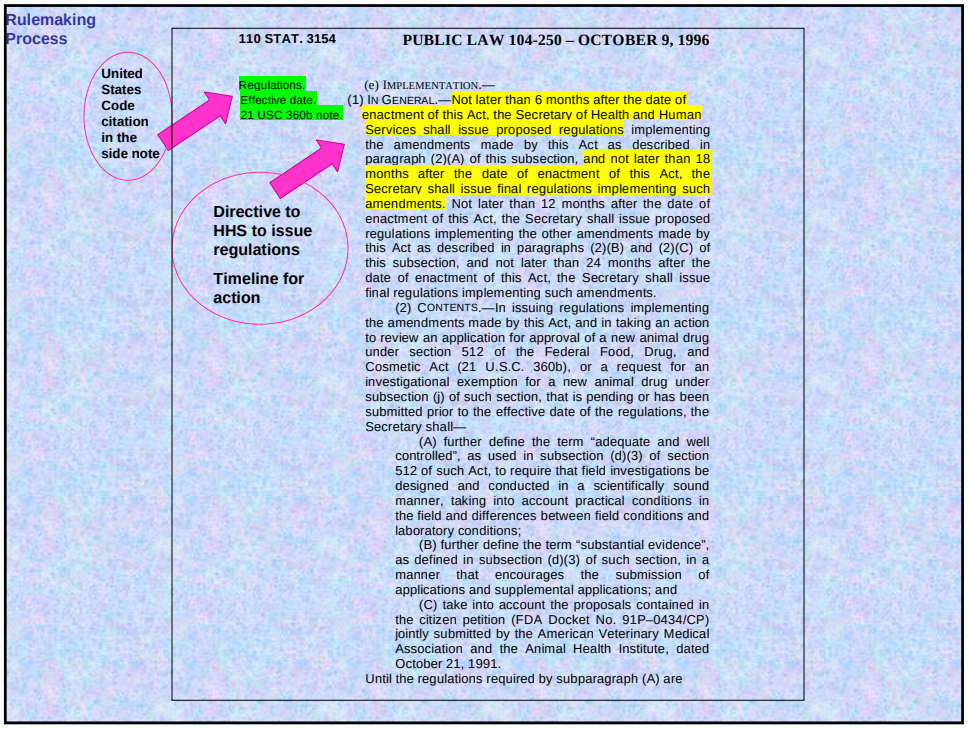


Rulemaking Instructions in the Law

FDA must issue regulations to implement the law.

- ✧ **Law sets a schedule for issuing proposed and final rules**
- ✧ **The agency must publish in *Federal Register* and follow APA notice and comment rulemaking process.**

Rulemaking Process



Rulemaking Process

Proposed Rulemaking

ADAA Example

- **Statute set a 6 month time limit for a Proposed Rule**
- **FDA published the proposed rule on May 8, 1997, about 7 months after the law was enacted, slightly past the deadline**

Rulemaking Process

Federal Register/Vol. 62, No. 89/ Thursday, May 8, 1997/Proposed Rules 25153

NPRM published May 8, 1997

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. 97N-0141]

Adequate and Well-Controlled Studies for Investigational Use and Approval of New Animal Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA), as directed by the Animal Drug Availability Act of 1996 (ADAA), is publishing a proposed regulation to further define the term "adequate and well-controlled" to require that field investigations be designed and conducted in a scientifically sound manner. Elsewhere in this issue of the Federal Register, FDA is reopening docket number 96N-0411 to receive comments regarding a concept, "good study practices," that is related to the definition of adequate and well-controlled studies.

The public has 75 days to comment

DATES: Written comments by July 22, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Herman M. Schoenemann, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1638.

SUPPLEMENTARY INFORMATION:

I. Background

Congress enacted the ADAA (Pub. L. 104-250) on October 9, 1996. Section 2(e) of the ADAA directs FDA to issue, within 6 months of its enactment, proposed regulations to further define the term "adequate and well-controlled" to require that field

Rulemaking Process

Federal Register / Vol. 62, No. 89 / May 8, 1997/ Proposed Rules 25157

3. New Sec. 514.117 is added to subpart B to read as follows:

Proposed Amendment to the CFR

§ 514.117 Adequate and well-controlled studies.

(a) *Purpose.* The primary purpose of conducting adequate and well-controlled studies of a new animal drug is to distinguish the effect of the new animal drug from other influences, such as spontaneous change in the course of the disease, normal animal production performance, or biased observation. One or more adequate and well-controlled studies are required to establish, by substantial evidence, that a new animal drug is effective. The characteristics described in paragraph (b) of this section have been developed over a period of years and are generally recognized as the essentials of an adequate and well-controlled study. Well-controlled, as used in the phrase adequate and well-controlled, emphasizes an important aspect of adequacy. FDA considers these characteristics in determining whether a study is adequate and well-controlled for purposes of section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b).. . .

Rulemaking Process

Final Rulemaking

ADAA

- ✧ FDA published the final rule on March 5, 1998, in time to meet the 18 month statutory deadline

The preamble of a final rule typically contains:

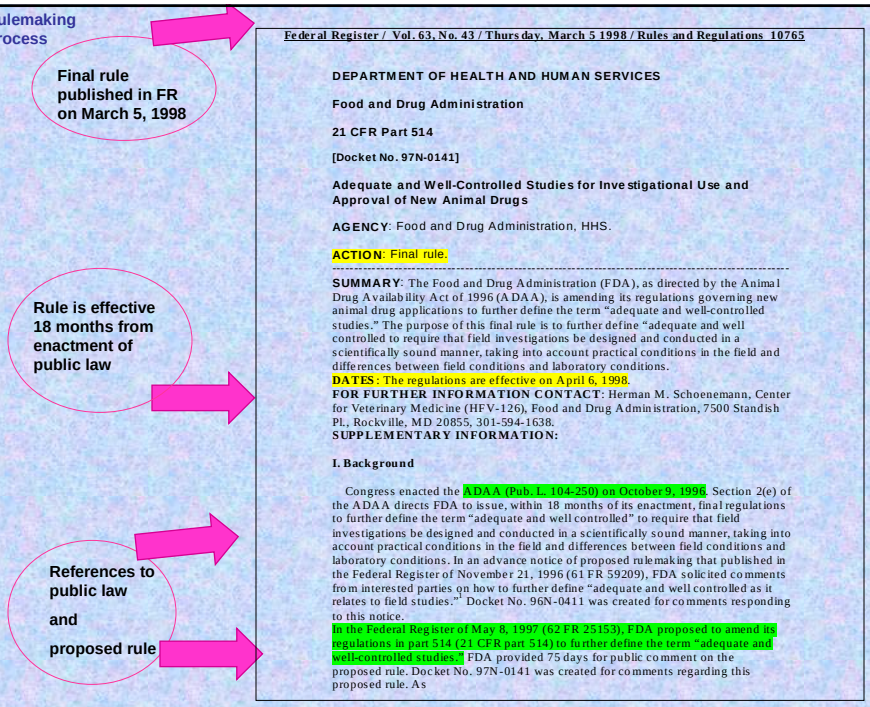
- ✧ Statement of the requirements in the law
- ✧ Cite to proposed rule and other rulemaking history
- ✧ Discussion and analysis of public comments received
- ✧ Justification for agency's final decisions

Rulemaking Process

Final rule published in FR on March 5, 1998

Rule is effective 18 months from enactment of public law

References to public law and proposed rule



Federal Register / Vol. 63, No. 43 / Thursday, March 5 1998 / Rules and Regulations 10765

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. 97N-0141]

Adequate and Well-Controlled Studies for Investigational Use and Approval of New Animal Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA), as directed by the Animal Drug Availability Act of 1996 (ADAA), is amending its regulations governing new animal drug applications to further define the term "adequate and well-controlled studies." The purpose of this final rule is to further define "adequate and well controlled to require that field investigations be designed and conducted in a scientifically sound manner, taking into account practical conditions in the field and differences between field conditions and laboratory conditions.

DATES: The regulations are effective on April 6, 1998.

FOR FURTHER INFORMATION CONTACT: Herman M. Schoenemann, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1638.

SUPPLEMENTARY INFORMATION:

I. Background

Congress enacted the ADAA (Pub. L. 104-250) on October 9, 1996. Section 2(e) of the ADAA directs FDA to issue, within 18 months of its enactment, final regulations to further define the term "adequate and well controlled" to require that field investigations be designed and conducted in a scientifically sound manner, taking into account practical conditions in the field and differences between field conditions and laboratory conditions. In an advance notice of proposed rulemaking that published in the Federal Register of November 21, 1996 (61 FR 59209), FDA solicited comments from interested parties on how to further define "adequate and well controlled as it relates to field studies." Docket No. 96N-0411 was created for comments responding to this notice.

In the Federal Register of May 8, 1997 (62 FR 25153), FDA proposed to amend its regulations in part 514 (21 CFR part 514) to further define the term "adequate and well-controlled studies." FDA provided 75 days for public comment on the proposed rule. Docket No. 97N-0141 was created for comments regarding this proposed rule. As

Rulemaking Process

Point-by-point analysis and response to public comments

Discussion of variations between proposed rule and final rule

Federal Register / Vol. 63, No. 43 / Thursday, March 5, 1998 / ….. 10768

A. Section 514.117(a)

1. AHI recommended that FDA clarify in proposed Sec. 514.117(a) that reports of adequate and well-controlled studies refer to reports of adequate and well-controlled "effectiveness" studies. Based on the following discussion, FDA does not find it necessary to make such a clarification.

Under section 512(d)(1)(E) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(d)(1)(E)), FDA must refuse to approve a new animal drug application if there is a lack of substantial evidence that the drug will have the effect it is purported or represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling. By definition, substantial evidence consists of one or more adequate and well-controlled studies on the basis of which experts qualified by scientific training and experience to evaluate the effectiveness of the drug could fairly and reasonably conclude that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in its proposed labeling (section 512(d)(3) of the act). Thus, it is clear and well established that adequate and well-controlled studies are studies intended to determine whether or not a drug is effective.

Because it is adequate and well-controlled studies and not just reports of adequate and well-controlled studies that provide a basis for determining whether a new animal drug is effective, and in some instances support a claim of target animal safety, FDA is deleting "Reports of" in the second to last sentence in proposed Sec. 514.117(a).

In that same sentence, FDA is also clarifying that adequate and well-controlled studies may be relied upon to support target animal safety but are not necessary to support claims of target animal safety. Studies intended to demonstrate safety need not be adequate and well-controlled studies (see section 512(d)(1) of the act, which states that in order to secure approval of a new animal drug, a sponsor must conduct adequate tests by all methods reasonably applicable to show whether or not such drug is safe). In proposed Sec. 514.117(a), FDA intended only to note that adequate and well-controlled studies intended to demonstrate whether a new animal drug is effective may be designed in a manner that also permits sponsors to simultaneously collect target animal safety data. If a sponsor needs to demonstrate through a field study that a new animal drug is safe for use in the target animal, the sponsor may do so by adequate tests by methods that are reasonably applicable or as part of an adequate and well-controlled study that is designed to determine the effectiveness of the new animal drug. Accordingly the second to last sentence in Sec. 514.117(a) will now provide that adequate and well-controlled studies, in addition to providing a basis for determining whether a new animal drug is effective, may also be relied upon to support target animal safety.

Rulemaking Process

Amendatory instructions

Text of new section 514.117 in part 514 of title 21

Federal Register / Vol. 63, No. 43 / Thursday, March 5, 1998 …. 10770

Lists of Subjects in 21 CFR Part 514

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 514 is amended as follows:

PART 514--NEW ANIMAL DRUG APPLICATIONS

1. The authority citation for 21 CFR part 514 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 360b, 371, 379e, 381.

2. Section 514.111 is amended by revising paragraph (a)(5) to read as follows:

§ **514.111 Refusal to approve an application**.

(a) * * *

(5) Evaluated on the basis of information submitted as part of the application and any other information before the Food and Drug Administration with respect to such drug, there is lack of substantial evidence consisting of one or more adequate and well-controlled studies by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and reasonably be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

* * * * *

3. New Sec. 514.117 is added to subpart B to read as follows:

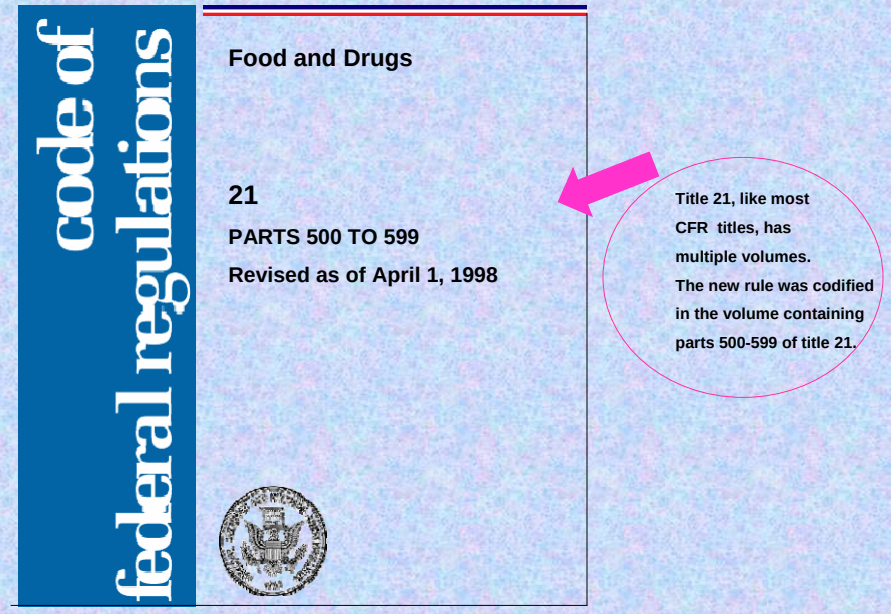
§ **514.117 Adequate and well-controlled studies**.

(a) *Purpose*. The primary purpose of conducting adequate and well-controlled studies of a new animal drug is to distinguish the effect of the new animal drug from other influences, such as spontaneous change in the course of the disease, normal animal production performance, or biased observation. One or more adequate and well-controlled studies are required to establish, by substantial evidence, that a new animal drug is effective. The characteristics described in paragraph (b) of this section have been developed over a period of years and are generally recognized as the essentials of an adequate and well-controlled study.

CFR Codification

ADAA

- FDA published the new animal drugs rule on March 5, 1998
- The rule was integrated into the April 1, 1998 revision of title 21 -- "Food and Drugs"



Rulemaking Process

Part Level Table of Contents, Authority Citations, and Source Notes

- A new entry in the table of contents at the part level to reflect the newly added section of regulatory text
- The authority citation below the table of contents
- The source note below the authority cite

Rulemaking Process

Section 514.117 added to Table of Contents

Authority Citation and Source Note

Title 21--Food and Drugs

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES--(Continued)

PART 514--NEW ANIMAL DRUG APPLICATIONS

Subpart A – General Provisions

* * *

Subpart B – Administrative Actions on Applications

514.100 Evaluation and comment on applications.
514.105 Approval of applications.
514.106 Approval of supplemental applications.
514.110 Reasons for refusing to file applications.
514.111 Refusal to approve an application.
514.112 Return of applications for animal feeds bearing or containing new animal drugs.
514.115 Withdrawal of approval of applications.
514.116 Notice of withdrawal of approval of application.
514.117 Adequate and well-controlled studies.
514.120 Revocation of order refusing to approve an application or suspending or withdrawing approval of an application.
514.121 Service of notices and orders.

Subpart C – Hearing Procedures

* * *

Subparts D-E [Reserved]

Subpart F – Judicial Review

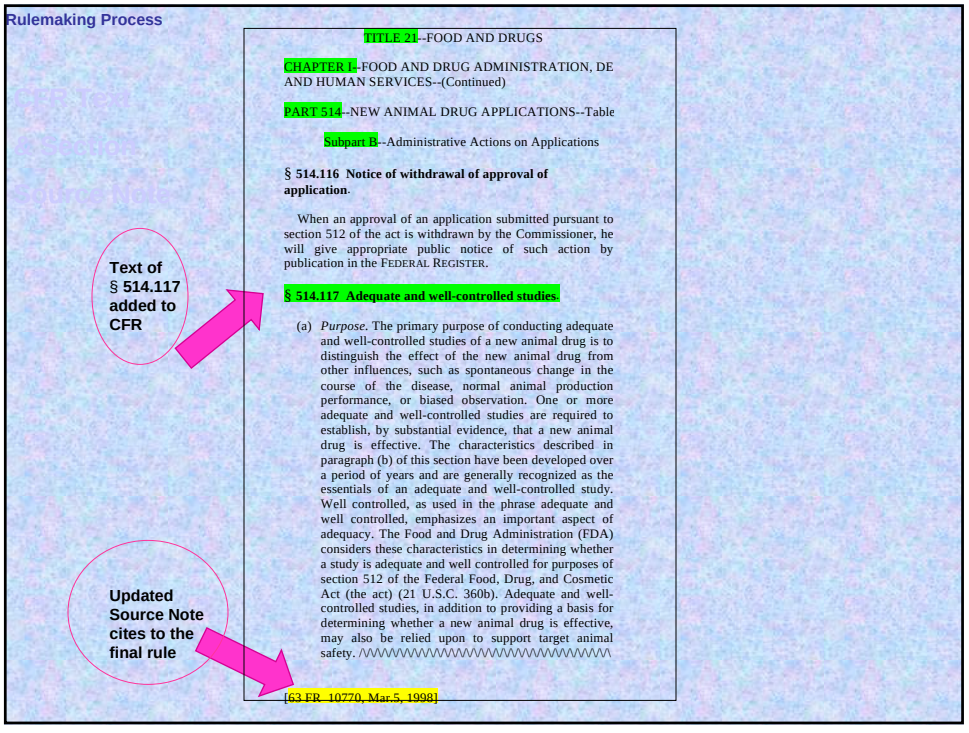
514.235 Judicial review.

AUTHORITY: 21 U.S.C. 351, 352, 360b, 371, 379e, 381

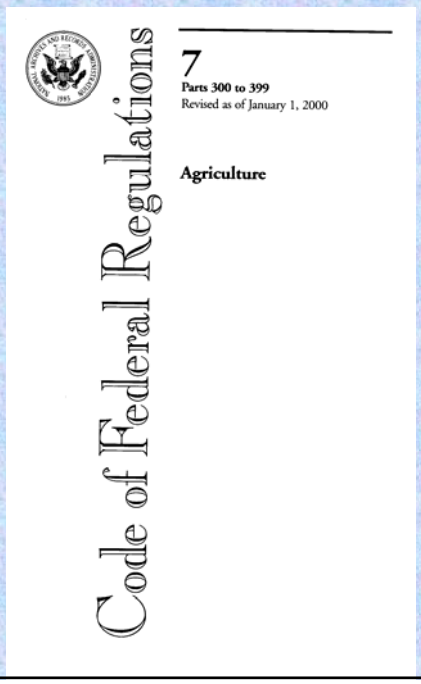
SOURCE: 40 FR 13825, Mar. 27, 1975, unless otherwise noted.

CFR Text, Section Level Source Notes, and Authority Citations

- The text of new section 514.117 inserted into CFR Title 21, Chapter I, Part 514, Subpart B
- A source note
- No separate authority citation for this section



CFR Research Tools



- Tables of Contents
- Incorporation by Reference Tables
- Table of CFR Titles and Chapters
- Alphabetical List of Agencies Appearing in the CFR
- Redesignation Tables
- List of CFR Sections Affected

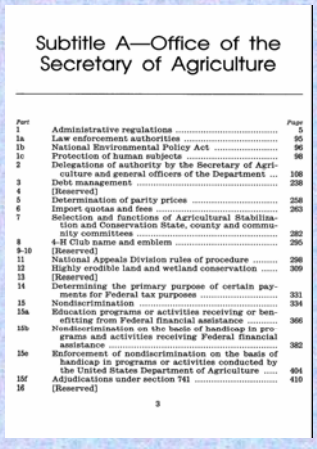
What research tools are in each printed volume of the CFR ?

- **At the front of each CFR volume, look for:**
  - ✧ Tables of contents to all material within the book
  - ✧ Tables of contents to the title, subtitle(s), chapter(s), and subchapter(s) within the book
- **At the back of each CFR volume, look for:**
  - ✧ A table of "Material Approved for Incorporation by Reference" (IBR)
  - ✧ A "Table of CFR Titles and Chapters"
  - ✧ An "Alphabetical List of Agencies Appearing in the CFR"
  - ✧ Redesignation Tables
  - ✧ A "List of CFR Sections Affected"

CFR Research Tools

Table of Contents to a Subtitle

Table of Contents shows page numbers for the beginning of each part



Subtitle A—Office of the Secretary of Agriculture

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CFR Research Tools

Part Level Table of Contents

Table of Contents lists the sections in the part and subparts

PART 1—ADMINISTRATIVE REGULATIONS

Subpart A—Official Records

Subpart B—Departmental Proceedings

Subpart C—Judicial Proceedings

Subpart D—Claims

Subpart E—Cooperative Production of Television Films

Subpart G—Privacy Act Regulations

Subpart H—Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes

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CFR Research Tools

Material Approved for Incorporation By Reference

- The incorporation by reference (IBR) table directs you to regulatory material not published in the FR & CFR
- IBR material has the force of law as though it were published in full text the FR & CFR
- Congress authorized IBR to enforce voluntary standards already used in science & industry
- Under the FOIA, the Director of the Federal Register must approve IBR to give it force and effect of law

CFR Research Tools

Table of CFR Titles and Chapters

- A list of all CFR titles, subtitles, chapters, and part spans in numerical order -- titles 1 to 50
- Includes the names of agencies assigned to CFR chapters
- A more detailed list is located in the *CFR Index and Finding Aids*, a separate publication

Alphabetical List of Agencies Appearing in the CFR

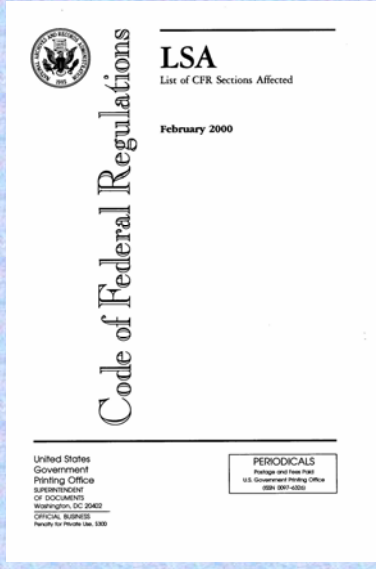
- A list of all agencies that publish in the CFR
- References to sub-agencies under main agencies
- Location of the regulations of each agency and sub-agency appear in the CFR by title, subtitle and chapter

Redesignation Tables

- A Redesignation Table helps you find the new location of parts and sections of regulations
- An agency publishes this table when it has done extensive reorganization and renumbering
- The table appears in the preamble of the rule document and is then included as a research tool in the back of the CFR

List of CFR Sections Affected (in a specific CFR volume)

- This list helps you track amendments in each CFR volume since 1986 by year and FR page number
- Lists the type of amendment and the text affected down to the paragraph level
- For years before 1986, use the seven separate volumes of the *List of CFR Sections Affected*
- A cumulative, monthly LSA is also published separately



How can the public participate in rulemaking ?

- Citizens have a right to express their views before an agency adopts final rules

- Each Federal Register document tells you:
  - ✧ Whether comments are requested
  - ✧ How, when and where to comment

How can the public participate in rulemaking ?

- Writing effective comments
  - ✧ Type neatly
  - ✧ Cite rulemaking by docket number and other identifying information
  - ✧ Include your name and address
  - ✧ Follow directions
  - ✧ Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes

Continue

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Go to: http://listserv.gsa.gov/archives/publaws-l.html

Select Join or *Leave the list* and follow instructions

Daily Federal Register Table of Contents (FEDREGTOC-L)

Go to: http://listerv.access.gpo.gov

Select FEDREG TOC-L, Join or *Leave,* and follow instructions

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	GPO Superintendent of Documents Web site: www.access.gpo.gov/su.docs/sale.html	Current prices, availability, and ordering information
	E-mail: info@fedreg.nara.gov	Assistance in locating a specific document
Code of Federal Regulations	*Federal Register* "Reader Aids" in back of printed issue, and online at: www.access.gpo.gov/su_docs/aces/aces140.html	CFR checklist appearing every Monday provides current prices and revision dates for each CFR volume
	Federal Register "Reader Aids" in back of printed issue, and online at: www.access.gpo.gov/su_docs/aces/aces140.html	Quarterly list in the first issue of January, April, July, and October. Lists CFR volumes issued for the year to date and projected for the next quarter
	List of CFR Sections Affected in back of printed issue and online at: www.access.gpo.gov/nara/lsa/aboutlsa.html	Monthly checklist of all CFR volumes currently available with revision dates and prices
Public Laws	*Federal Register* "Reader Aids" in back of printed issue and online at: www.access.gpo.gov/su_docs/aces/aces140.html	Continuing lists of public bills that have become law. Includes law number and GPO order information.